STATE OF MICHIGAN

IN THE SUPREME COURT

ON APPEAL FROM THE COURT OF APPEALS
(Collins, P.J. (not participating) and Murphy and Jansen, J.J.)

TAMARA TAYLOR and LEE ANNE RINTZ, on behalf of themselves and all other similarly situated,

Plaintiffs-Appellees,

vs.

GATE PHARMACEUTICALS, A DIVISION OF TEVA PHARMACEUTICALS, USA, INC.,

Defendant,

SMITHKLINE BEECHAM CORP.,

Defendant-Appellant,

ZENITH GOLDLINE PHARMACEUTICALS, INC.; ABANA PHARMACEUTICALS, INC.; RICHWOOD PHARMACEUTICAL CO., INC.; ION LABORATORIES, INC.; MEDEVA PHARMACEUTICALS, INC.; A.H. ROBINS CO., INC.; WYETH-AYERST LABORATORIES CO.; AMERICAN HOME PRODUCTS CORP.; INTERNEURON PHARMACEUTICALS, INC.; CAMALL CO.; PEDRITO GALUPA, M.D.; and WILLIAM R. TUURI, M.D.,

Defendants.
_____/

Supreme Court Docket
No. 120624

BRIEF ON APPEAL FOR SMITHKLINE BEECHAM CORPORATION

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QUESTION PRESENTED FOR REVIEW

WHETHER MCL 600.2946(5), WHICH PROVIDES THAT A MANUFACTURER OR SELLER OF A DRUG IS NOT LIABLE IN A PRODUCTS LIABILITY ACTION IF THE DRUG WAS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION ("FDA"), AND BOTH THE DRUG AND ITS LABELING WERE IN COMPLIANCE WITH THAT APPROVAL AT THE TIME THE DRUG LEFT THE CONTROL OF THE MANUFACTURER OR SELLER, IS AN UNCONSTITUTIONAL DELEGATION OF LEGISLATIVE AUTHORITY?

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STATUTES, COURT RULES AND OTHER AUTHORITIES

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STATEMENT OF FACTS

Defendant SmithKline Beecham Corporation appeals by leave granted from the published decision of the Michigan Court of Appeals, authored by Judge William Murphy, and concurred in by Judge Kathleen Jansen (with former Judge Jeffrey Collins not participating), released November 30, 2001 (Appx 40a-50a, Court of Appeals opinion). That decision affirmed the January 8, 1999 order by former Wayne County Circuit Court Judge Marianne O. Battani (Appx 36a), denying defendants' motions for summary disposition pursuant to an opinion dated November 24, 1998 (Appx 20a).

Plaintiffs, Tamara Taylor and Lee Anne Rintz, "on behalf of themselves and all others similarly situated," filed this suit alleging medical malpractice and product liability claims arising out of their alleged use of the prescription drugs fenfluramine, phentermine and dexfenfluramine (Appx 3a, plaintiffs' third amended class action complaint).[1]

Plaintiffs below and on appeal often incorrectly characterize their allegations as involving claims that a single drug, "Fen-Phen", was involved which had been declared as unsafe and which had been "withdrawn" from the market by the FDA. For purposes of clarification, the popular label "Fen-Phen" is a non-authorized slang used by some to refer to a combined use of two different drugs used in the treatment of obesity: generically known as **fen**fluramine hydrochloride and **phen**termine hydrochloride. A third drug involved in these complaints, dexfenfluramine hydrochloride, is a derivative of fenfluramine. There was never a product on the market which contained both

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[1] Plaintiffs are seeking to bring this case as a class action. No determination has yet been made by the trial court as to class certification. The case has been stayed by the trial court pending this appeal.

fenfluramine and phentermine in a single tablet or capsule (see 6/19/98 Reply Brief by SmithKline, p 2, Appx 18a-19a).

"Fenfluramine" hydrochloride is the generic name for Pondimin®. "Dexfenfluramine" hydrochloride is the generic name for Redux®. These drugs, Pondimin and Redux, were voluntarily withdrawn from the market in 1997. This defendant, SmithKline, sold "phentermine" hydrochloride under the brand name Fastin®, which was approved for safety and efficacy by the Food and Drug Administration (FDA) and has been on the market since 1973. Neither Fastin®, nor phentermine hydrochloride generally, has been deemed by the FDA to be unsafe, and Fastin® remains on the market. (Id.)

Motions For Summary Disposition

Initially, co-defendants A.H. Robins Company, Inc., Wyeth-Ayerst Laboratories and American Home Products Corporation filed a motion for summary disposition. SmithKline joined in that motion, as did the other co-defendant drug manufacturers and sellers. The defendants submitted that the complaint should be dismissed with prejudice since plaintiffs' claims are unenforceable pursuant to the provisions of MCL 600.2946(5). MCL 600.2946(5) provides that a manufacturer or seller of a drug is not liable in a products liability action if the drug was approved by the United States Food and Drug Administration ("FDA") and both the drug and its labeling were in compliance with that approval at the time the drug left control of the manufacturer or seller.

Plaintiffs filed a response to the motion asserting that section 2946(5) was unconstitutional on several grounds--that it is an impermissible delegation of judicial and legislative authority, that it improperly denies access to the courts, and that it violates equal protection and due process guaranties. Plaintiffs further moved for summary

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disposition, requesting that if the court found the statute unconstitutional that it strike down the entire 1995 Tort Reform Act, 1995 PA 161 and 1995 PA 249.

A hearing was held on the motions on September 11, 1998. The trial court took the matter under advisement, requesting further briefing on the issue of impermissible delegation of legislative authority. Such briefs were filed by the parties, including this defendant.

Subsequently, the trial court issued an opinion on November 24, 1998, striking down section 2946(5) as an unconstitutional delegation of legislative authority (Appx 20a-35a). The trial court, however, denied plaintiff's other claims of unconstitutionality, finding that the statute does not unconstitutionally delegate judicial authority, does not improperly deny access to the courts, and does not violate equal protection or due process guaranties (Id.). Further, the trial court denied plaintiff's request to strike down the entire 1995 Tort Reform Acts as unconstitutional since the remaining portions of the acts do not turn on the enforcement of section 2946(5) (Id.).

Court of Appeals Proceedings

Defendant SmithKline filed an application for leave to appeal with the Court of Appeals on or about January 29, 1999. Similar applications for leave to appeal were filed by co-defendants Medeva Pharmaceuticals, Inc., Gate Pharmaceuticals, A.H. Robins Co., Inc., Wyeth-Ayerst Laboratories, Co., and American Home Products Corp. On May 24, 1999, the Court of Appeals entered orders granting the applications and consolidating the cases.

On November 30, 2001, the Court of Appeals released a published decision, authored by Judge William Murphy, and concurred in by Judge Kathleen Jansen (with

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former Judge Jeffrey Collins not participating), which affirmed the order by the Wayne County Circuit Court denying summary disposition (Appx 40a-50a).

The two-member panel of the Court of Appeals held that MCL 600.2946(5) is unconstitutional because it "works an unconstitutional delegation of legislative authority." (Id.)

Defendants thereafter filed applications for leave to appeal to this Court which were granted by orders of July 2, 2002. This brief is submitted by SmithKline Beecham in support of the constitutionality of MCL 600.2946(5).

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ARGUMENT

MCL 600.2946(5) IS A LEGISLATIVE POLICY DECLARATION OF THE STANDARD OF CARE OWED BY A DRUG MANUFACTURER, FOR COMPLIANCE WITH WHICH TORT LIABILITY WILL NOT LIE, AND WHICH DOES NOT IMPLICATE OR VIOLATE THE CONSTITUTIONAL PROHIBITION ON DELEGATION OF LEGISLATIVE AUTHORITY.

MCL 600.2946(5) is a legislative policy declaration. The Legislature has determined that if a drug manufacturer and/or seller has obtained FDA approval of a drug product, the manufacturer and/or seller has acted sufficiently prudently so that no tort liability may lie. Such policy determination and declaration regarding tort liability is indisputably within the authority of the Legislature. Delegation of legislative authority is simply not a principle applicable or germane to section 2946(5).

A. Standard Of Review And Presumption Of Constitutionality.

The granting of a motion for summary disposition is reviewed de novo, as is the determination of the constitutionality of a statute. McDougall v Schanz, 461 Mich 15; 597 NW2d 148 (1999), Wickens v Oakwood Healthcare System, 465 Mich 53, 59; 631 NW2d 686 (2001).

It is axiomatic that challenged legislative judgment is accorded a presumption of constitutionality and that plaintiffs bear the burden to overcome the presumption of constitutionality afforded to legislative enactments. McDougall v Schanz, 461 Mich 15; 597 NW2d 148 (1999) (upholding constitutionality of 1986 tort reform provision governing qualifications of expert witness in medical malpractice actions); Shavers v Attorney General, 402 Mich 554, 613; 267 NW2d 71 (1978), cert den 442 US 934 (upholding constitutionality of automobile no fault legislation); Bissell v Kommareddi, 202 Mich App 578; 509 NW2d 542 (1993), lv den 446 Mich 861 (1994) (upholding constitutionality of 1986 tort reform amendment to statute of limitations), Ullery v Sobie,

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196 Mich App 76; 492 NW2d 739 (1992) (upholding constitutionality of cap of five percent on comparative negligence for failing to wear a seat belt).

As stated by the Court in Council of Organizations v Governor, 455 Mich 557, 570; 566 NW2d 208 (1997), deference is to be given to acts of the Legislature, regardless of the wisdom associated with such legislation:

> This Court gives deference to a deliberate act of the Legislature, and does not inquire into the wisdom of its legislation. The power to declare a law unconstitutional should be exercised with extreme caution and never where serious doubt exists with regard to the conflict. Every reasonable presumption or intendment must be indulged in favor of the validity of the act, and it is only when the invalidity appears so clearly as to leave no room for reasonable doubt that it violates some provision of the Constitution that a court will refuse to sustain its validity. [Id. at 570; citations omitted.]

See also Evans Product Co v Fry, 307 Mich 506, 534-535; 12 NW2d 448 (1943).

B. The 1995 Tort Reform Acts And FDA Drug Approval Framework.

In 1995, the Legislature adopted two tort reform acts, 1995 PA 161 and 1995 PA 249. These bills impact tort law in several areas, including affording protection, in MCL 600.2946, to drug manufacturers when the drug has been approved by the FDA.[2]

MCL 600.2946(5) provides, in pertinent part:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administrations, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

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[2] Other provisions in these acts include amendments to the venue statute, MCL 600.1629; new expert witness qualification requirements, MCL 600.2955; elimination of joint liability in most tort actions, MCL 600.2956; and caps on non-economic damages, MCL 600.2946a.

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MCL 600.2946(5) also provides for exceptions based on intentional withholding from, or misrepresentations to, the FDA of information concerning the drug or illegal payment to an official of the FDA for the purpose of securing or maintaining approval. These exceptions are not at issue here.

Some of the reasons behind adoption of the 1995 tort reform acts were discussed in the House Legislative Analysis Section:

> Critics of the tort (or liability lawsuit) system, particularly manufacturers and others in the business sector, characterize it as a hidden tax that stifles innovation, suppresses enterprise, restricts the availability of products and services, and reduces the ability of Michigan businesses to compete in the global economy. They allege that an ever-increasing number of claims and lawsuits, the ever present prospect of large verdicts or awards, and ever expanding theories of liability not only add to the cost of doing business and to the price of products but help to create an atmosphere of unpredictability that threatens the ability of businesses to plan and conduct their affairs. The problem is described as especially acute in the area of product liability.
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> * * *
>
> Critics argue that its unpredictability gives the tort system the look of a lottery: people file claims against as many potential defendants as possible hoping to find one or more "deep pockets" and a sympathetic jury. This gives rise to what critics insist are frivolous suits, suits without real merit. Yet these suits can be costly to defend. Sometimes it is considered prudent to settle instead. What is worse, cases that appear frivolous to a defendant can be lost. This is particularly to be the case when large, powerful institutions or relatively wealthy (or well-insured) businesses, regardless of size are pitted against injured individuals: sympathetic juries will compensate the injured for the harm they have suffered without regard to the culpability of those who will be forced to pay. The unpredictability leads, as well, to higher insurance premiums. Smaller businesses are also at risk since they often cannot afford liability insurance or the cost of litigation. [House Legislative Analysis, SB 344, June 8, 1995, p 1.]

The benefits resulting from the inclusion of section 2946, providing a protection from tort liability to a drug manufacturer if the drug was approved by the FDA, were stated in the House Legislative Analysis as follows:

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> [Drug] companies whose products receive FDA approval for safety or effectiveness are not liable unless the company deceived the government in the approval process. Drug companies spend large sums of money and expend enormous energy getting approval for their products. Many valuable products never reach the market or are withdrawn because of successful lawsuits (or the threat of future lawsuits) even though there is no medical evidence that they are harmful. [Id. at p 12.]

Pursuant to the federal Food, Drug and Cosmetic Act, 21 USC 301-92, the FDA has comprehensive regulatory authority over drug formulation, production, testing and labeling. 21 USC 355(a)-(n), and the regulations enacted to implement these provisions, 21 CFR 300-369, set forth detailed requirements for the application for approval and approval of new drugs, as well as for the withdrawal of approval of a drug. The extensive nature of the FDA's approval process for new drugs has been described by many commentators. See Del Giorno, Supposing and Regulating Medical Innovation, the Architecture of Government Regulation of Medical Products, 82 Va L Rev 1753 (Nov, 1996); Merrill, Federal Pre-Emption of Prescription Drug Labeling: Antidote for Pharmaceutical Overdosing on State Court Jury Decisions in Products Liability Cases, 22 JP Marshall L Rev 629, Spring 1989.

C. Section 2946(5) Does Not Delegate Lawmaking Power, But Simply Establishes When a Manufacturer's Conduct Will Be Considered Reasonable As A Matter Of Law For Purposes Of Tort Liability, The Modification Of Which Is Clearly Within The Legislature's Power.

Const 1963, art IV § 1, provides that "the legislative power of the State of Michigan is vested in a senate and house of representatives." Pursuant to this provision, the Legislature cannot constitutionally delegate the power to make or repeal a law. However, delegation of legislative power is not implicated by MCL 600.2946(5).

MCL 600.2946(5) does not involve a delegation of power to make a law at all. Rather, it is simply a legislative alteration of the common law duty/reasonable care

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element in a drug product liability tort case--a power indisputably within the constitutional authority of the Legislature.

Under Michigan common law, product liability under negligence or breach of warranty theories turns on "'a departure from proper standards of care so that the tort is essentially a matter of negligence.'" Prentis v Yale Manufacturing, 421 Mich 670, 692-693; 365 NW2d 176 (1984). MCL 600.2946(5) is a legislative policy determination with regard to the required standard of conduct in a product liability case involving allegations that a drug is "defective" or "unreasonably dangerous." The Legislature has simply determined that where a manufacturer has obtained from the FDA approval of the safety and efficacy of its drug, and has complied with the FDA's approval in the labeling and manufacture of the drug, the manufacturer has acted sufficiently reasonably such that product tort liability will not lie.

The Legislature's action in section 2946(5) is comparable to what was or has been done as a matter of common law by courts in some states. Some courts have found that under such circumstances a prescription drug is, as a matter of law, a reasonably safe product. In Lewis v Baker, Richardson-Merrell, Inc, 243 Or 317; 413 P2d 400 (1966), the Oregon Supreme Court held as a matter of common law that a drug approved by the Food and Drug Administration, and marketed properly under federal regulation was, as a matter of law, a reasonably safe product. See, also, Leibowitz v Ortho Pharmaceutical Corp, 224 Pa Super 418; 307 A2d 449 (1973). While such cases have subsequently been modified with respect to warnings, or even overruled as a matter of common law and judicial policy, see McEwen v Ortho Pharmaceutical Corp, 270 Or 375; 528 P2d 522 (1974), overruling Lewis, supra, these decisions are illustrative of what the Legislature really has done here. There has been

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no delegation of Legislative power, but merely a Legislative determination of when, as a matter of law, a manufacturer has acted sufficiently reasonably, solely for purposes of defining the limits of a cognizable product liability claim under Michigan law.

Such a determination is well within the Legislature's constitutional authority. There is no question that the Legislature has the authority to modify, change or abolish existing statutory and common-law remedies. See McDougall v Schanz, 461 Mich 15; 597 NW2d 148 (1999), Shavers v Attorney General, supra at 612, n 36 (1978); Dyke v Richard, 390 Mich 739, 745; 213 NW2d 185 (1973); Bean v McFarland, 280 Mich 19; 273 NW 332 (1937). As the Court in Shavers recognized:

> Article 3, section vii of our Constitution states that "the common law and the statute laws now in force, not repugnant to this constitution, shall remain in force until they expire by their own limitations, or are changed, amended, or repealed." [Shavers, supra, at 612 n 36.]

Quoting from Silver v Silver, 280 US 117, 122; 50 SCt 57; 74 L Ed 221 (1929), the Shavers Court further recognized that the "Constitution does not forbid the creation of new rights or the abolition of old ones recognized by the common law, to obtain a permissible legislative object." Shavers, supra, at 612, n 36.

In the context of the 14th Amendment, the United States Supreme Court and this Court have both expressly recognized that it is the Legislature which should make policy decisions regarding the wisdom and utility of legislation. In Ferguson v Skrupa, 372 US 726; 83 SCt 1028; 10 L Ed2d 93, 97 (1963), the Supreme Court stated:

> [C]ourts do not substitute their social and economic beliefs for the judgment of legislative bodies, who are elected to pass laws. As this Court stated in a unanimous opinion in 1941, "We are not concerned...with the wisdom, need, or appropriateness of the legislation."
>
> Legislative bodies have broad scope to experiment with social problems and this Court does not sit to "subject the Estate to an intolerable supervision hostile to the basic principles of our government and wholly beyond the protection with which the general clause of the 14th

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amendment was intended to secure." [Quoted in Shavers, supra, p 614, n 38.]

The Court in McDougall v Schanz, 461 Mich 15; 597 NW2d 148 (1999), recently reaffirmed the Legislature's power to define a cause of action, including the element of standard of care. The Court upheld as constitutional the statute prescribing the minimum qualifications of expert witnesses in medical malpractice actions, MCL 600.2169, a provision in the 1993 tort reform act, 1993 PA 78. Finding that this statute is a Legislative policy declaration of substantive law and that the Legislature is constitutionally empowered to modify the applicable standard of care, the Court in McDougall stated:

> Because the Legislature is authorized to change a common-law cause of action or abolish it altogether, O'Brien v Hazelett & Erdal, 410 Mich 1, 15; 299 NW2d 336 (1980), it necessarily has the ability to "circumscrib[e] those qualified to give the requisite proofs to establish the elements of the cause of action." 218 Mich App 518 (Taylor, P.J., dissenting). The applicable standard of care is an essential element in a medical malpractice action. Locke v Pachtman, 446 Mich 216, 222; 521 NW2d 786 (1994). Section 2169 essentially modifies that element to require that proof of malpractice "emanate from sources of reliable character as defined by the Legislature." 218 Mich App 518 (Taylor, P.J., dissenting). [emphasis added.]

The Court in McDougall also recognized that the Legislature (not the judiciary) is empowered by the Constitution to balance policy considerations and adopt legislation to address societal concerns:

> We agree with the Court of Appeals dissent in McDougall that the statute "reflects a careful legislative balancing of policy considerations about the importance of the medical profession to the people of Michigan, the economic viability of medical specialists, the social costs of 'defensive medicine,' the costs of malpractice insurance, and manifold other factors, including, no doubt, political factors - all matters well beyond the competence of the judiciary to reevaluate as justiciable issues." [quoting 218 Mich App 518.]

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In Cox v Board of Hospital Managers for the City of Flint, ___ Mich ___; ___ NW2d ___ (2002), this Court acknowledged the fact that the Legislature in MCL 600.2912a had redefined the common law duty standard in medical malpractice actions against physicians. Deferring to that legislative exercise of power, the Court in Cox directed that juries be properly instructed in accord with the Legislature's revision of the common law. See also MCL 333.20965, in which the Legislature elected to bar a cause of action for ordinary negligence of medical personnel when giving emergency medical treatment, limiting such claims to gross negligence or willful misconduct.

With the adoption of MCL 600.2946(5), the Legislature has simply modified the common law and declared that, as a matter of law, a drug manufacturer/seller has acted with reasonable or due care and/or that its product is not defective (unreasonably dangerous) within the meaning of product liability tort law when it has secured FDA approval of a product it is marketing. MCL 600.2946(5) does no more than articulate the maximum standard of care required by a manufacturer, upon compliance with which tort liability will be legislatively abrogated. By so doing, the Legislature has exercised its constitutional power to modify and change existing common law. As the Shavers Court recognized, such legislative action is within the constitutional authority of the legislative branch.

In adopting section 2946(5), the Legislature has done nothing more than what the appellate courts of this state have done as a matter of common law in the past. In cases involving overriding public policy concerns, the courts have determined what constitutes reasonable care. Recognizing the absence of any legislative policy declaration, the Court in Williams v Cunningham Drug Stores, Inc, 429 Mich 495, 501-502; 418 NW2d 381 (1988), addressed and decided the issue of whether landowners

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have a duty to provide police protection to invitees. In Moning v Alfono, supra, the Court adopted, in the absence of a legislative policy, a rule addressing the standard of care owed to children by slingshot manufacturers and sellers. The Legislature unquestionably also may make such policy determinations, especially since it is charged in the constitution to legislate substantive matters.

Likewise, compliance with industry and/or governmental standards has repeatedly been held by the appellate courts in this state to be admissible evidence relevant to the determination of whether there has been a breach of the standard of care owed in a tort or products liability action. Marietta v Cliff Ridge, Inc, 385 Mich 364; 189 NW2d 208 (1971); Owens v Allis-Chalmers Corp, 414 Mich 413; 326 NW2d 372 (1982). Thus, even the courts have recognized that the standards of other entities are relevant and may be considered in a negligence case.

The predecessor to the current version of MCL 600.2946 contained a similar declaration that governmental and/or industry standards were admissible evidence in a products liability action.[3]

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[3] The 1995 amendment rewrote section 2946, which prior thereto read:

> (1) It shall be admissible as evidence in a products liability action that the manufacture, construction, design, formula, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, advertising, packaging, or labeling was done pursuant to the generally recognized and prevailing nongovernmental standards in existence at the time the product was sold or delivered by the defendant to the initial purchaser or user.
>
> (2) It shall be admissible in evidence in a products liability action that the manufacture, construction, design, formula, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, advertising, packaging, or labeling was done pursuant to the federal and state law, rules, or regulations in effect at

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In Owens, supra, the Court addressed the relevancy of compliance with governmental and industrial standards in a products liability case, both under the common law and the prior version of section 2946. The Court in Owens reaffirmed that at common law compliance with governmental and industrial standards is admissible at trial as relevant evidence to be used to determine whether or not the standard of care has been met. 414 Mich at 422.

With the adoption of the 1995 tort reform acts, the Legislature here has essentially gone one, constitutionally permissible, step further in providing that compliance with certain federal governmental standards (by the FDA) is conclusive on the issue of due care. With the adoption of the 1995 amendment to MCL 600.2946, which included the addition of subsection 5, the Legislature has simply broken from the common law and determined that compliance with the FDA rules is more that just evidence--that such standard establishes that a manufacturer and /or seller has complied with the standard of reasonable care, and that, as a result, there is no liability.[4] This is simply a policy decision to use the FDA approval as the measuring stick for

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> the time the product was sold or delivered by the defendant to the initial purchaser or user.
>
> (3) Evidence of a change in the philosophy, theory, knowledge, technique, or procedures of or with regard to the manufacture, construction, design, formula, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, advertising, packaging, or labeling made, learned, placed in use or discontinued after the event of death or injury to person or property shall not be admissible in a product liability action to prove liability.

[4] Section 2946, arguably, is a logical extension of and in compliance with federal preemption law and would be justified even as a matter of common law. See Boulahanis v Prevo's Family Market, Inc, 230 Mich App 131; 583 NW2d 509 (1998) lv den 459 Mich 957 (1999) cert den 530 US 1203 (2000).

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reasonable conduct and satisfaction of the duty of care owed by a drug manufacturer and/or seller for tort liability purposes. There is no delegation of legislative power to make laws.

The Legislature has not purported to regulate or determine what products are safe or appropriate for distribution, or to delegate that determination to the FDA. The Legislature has merely made a policy determination with respect to the parameters of product tort liability and, what, in effect, constitutes sufficiently due or reasonable care, so as to preclude imposition of tort liability.

D. Alternatively, Section 2946(5) Does Not Delegate Power But Properly Provides For Certain Consequences Upon The Occurrence Of Certain Actions By A Manufacturer And The FDA.

In contexts other than tort liability, the appellate courts in this state and others have recognized the propriety of legislation providing for a certain regulatory consequence upon the action of a third party, including federal administrative agencies, and those in other states. The Court in Michigan Baptist Homes & Development Co v City of Ann Arbor, 55 Mich App 725; 223 NW2d 324 (1974), aff'd 396 Mich 660; 242 NW2d 749 (1976), found constitutional a statutory provision which was conditional based on a federal agency determination. In this case, the Court of Appeals addressed an allegation of unlawful delegation of legislative authority in the context of the General Property Tax Law, which turned upon federal agency determinations under the National Housing Act of 1959.

Plaintiff in Michigan Baptist Homes was a Michigan nonprofit corporation organized and operated for the purpose of acquiring and maintaining nursing and convalescent homes and homes for the aged. The issue before the Court was whether the home operated by the plaintiff was entitled to charitable status and thus exempt

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from taxation under the General Property Tax Act, specifically MCL 211.7 and MCL 211.9. MCL 211.7(d) defined a nonprofit corporation or organization as one incorporated under the laws of the state of Michigan "not otherwise exempt from general and valorem real and personal property taxes operating a housing facility or project qualified, built or financed under section 202 of the National Housing Act of 1959, as amended." 55 Mich App at 732. The home in question did not qualify as a housing facility or project, built or financed under the National Housing Act of 1959.

The plaintiff in Michigan Baptist Homes argued that it was an unconstitutional delegation of power to a federal agency to limit the exemption provided under the General Property Tax Act to a nonprofit corporation who has obtained financing under the National Housing Act. The Court of Appeals rejected this argument, stating:

> The Federal official does not made a determination as to who shall receive the exemption. He merely determines which nonprofit corporations are eligible to receive Federal financing under §202. Furthermore, this provision for Federal financing of housing for the elderly was no doubt created for the lowest income type of housing, since it is almost impossible to obtain sufficient financing for these projects from other sources. In other words, our Legislature intended that the tax-exempt status be extended to the lowest income type of housing. The Legislature has merely created a special category of low-income housing for the elderly which is to be granted tax-exempt status. [55 Mich App at 737-738.][5]

Another legislative enactment analogous to MCL 600.2946(5) is a Wisconsin statute addressing anatomical gifts. In Williams v Hoffman, 66 Wis2d 145; 223 NW2d 844 (1974), the Wisconsin court was asked to determine the constitutionality of a provision of the Uniform Anatomical Gift Act which immunized people who acted in good faith in accord with the anatomical gift laws of other states or foreign countries. Among

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the arguments raised was that this statute unlawfully delegated Legislative power to foreign jurisdictions to determine Wisconsin law. The Court rejected this argument stating:

> [O]n the merits, this portion of sec. 155.06(6)(c), Stats., does not delegate legislative power to foreign jurisdictions. The provision only states, in effect, that if an act is done in good faith in another jurisdiction that is considered lawful in that jurisdiction, it will be accorded similar status in Wisconsin. This provision is designed to solve conflict-of-laws problems and is justified on principles of comity, and as an effort to provide physicians greater certainty concerning their potential liability. We conclude, therefore, that sec. 155.06(7)(c) does not empower foreign jurisdictions to make Wisconsin laws; rather, the section only recognizes the lawfulness of actions taken in such jurisdictions in accord with their own laws. The section does not unlawfully delegate legislative power. [Williams at 889, emphasis added.][6]

Other federal measuring sticks have been utilized by our Legislature. For example, the interest statute, MCL 600.6013, adopts for the interest rate on complaints filed on or after January 1, 1987 the average interest rate paid at auctions of five-year United States treasury notes plus one percent. MCL 600.6013(6).

The lower courts relied heavily on two decisions by this Court, both over 48 years old, when declaring section 2946(5) unconstitutional--Coffman v State Bd of Examiners, 331 Mich 582; 50 NW2d 322 (1951) and Colony Town Club v Mich Dept of

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[5] In affirming the Court of Appeals decision, the Supreme Court declined to address this constitutionality issue.

[6] Statutes which simply adopt external standards or contingencies have been upheld as constitutional by other states. See Fulmer v Jensen, 221 Neb 582, 379 NW2d 736 (1986); In re Hansen, 275 NW2d 790 (Minn 1978); Commissioner of Revenue v Massachusetts Mutual Life Ins Co, 384 Mass 607, 428 NE2d 297 (1981); McHenry State Bank v Harris, 89 Ill2d 542, 434 NE2d 1144 (1982); State v Wakeen, 263 Wis 401, 57 NW2d 364 (1953); Lucas v Maine Com of Pharmacy, 472 A2d 904 (Me 1984); and Madrid v St Joseph Hos, 122 NM 524, 928 P2d 250 (1996). SmithKline refers to and incorporates by reference that portion of co-defendant American Home Products' appeal brief which discussed such cases.

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Compensation Com, 301 Mich 107; 3 NW2d 28 (1942). Defendant submits that these decisions are either inapposite to the statutory provision at issue in this case, or wrongly decided.

In Coffman, the statute at issue addressed the requirements for the taking of an examination in optometry for licensing purposes. The statute, among others, provided that the applicant be a graduate of an optometric school or college rated as class A or class B by the International Association of Boards of Examiners in Optometry. The statute also allowed the board to fix the number of hours of actual clinical instruction and recitation necessary to constitute a year's attendance course at an optometric school or college.

While the Court held it improper to delegate to these boards the power to rate optometric schools and/or colleges, the Court held that it was proper to allow the board to set up minimum standards, even if such standards were higher than the minimum set up in the legislation.

In Colony, the defendant appealed a determination of the Unemployment Compensation Appeal Board that defendant was not a corporation organized and operated exclusively for literary or educational purposes for purposes of the Michigan unemployment compensation act. For purposes of the Federal social security tax and income taxes (which contained substantially the same exemption as under the Michigan unemployment compensation act), the defendant had been previously determined to be exempt under the federal statutes. The defendant claimed that the Michigan Board was bound by the federal bureau's determination based, among others, on a reference in an amendment which provided that the term employment shall not include "[a]ny service not included as employment under title 9 of the social security act." 301 Mich at 113.

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Finding that "it was doubtful" the Legislature intended to delegate such authority, the Court in Colony found that if the statute attempted to delegate to the federal agency the final decision "regarding the interpretation and construction to be placed upon a State statute" it was improper.

Unlike the statutes at issue in Coffman and Colony, section 2946(5) does not ask the FDA to legislate what is a qualified drug under the Michigan statute or to otherwise interpret a Michigan statute. Rather, the Legislature has determined that a drug manufacturer/seller has met the a sufficient standard of care so as to eliminate tort liability where the manufacturer has pursued and secured FDA approval before marketing its drug. Rather, the Legislature has simply determined a legal consequence to be given to such FDA approval. This is a constitutional declaration.

E. Alternatively, Even Assuming Arguendo That It Would Be Unconstitutional For The Legislature To Enact Legislation Which Would Have Consequences Impacted By Future FDA Determinations, Which Is Denied, As Applied Here To This Defendant The Statute Would Still Be Constitutional As There Was An Existing Federal Agency Determination As To This Defendant's Product At The Time Section 600.2946(5) Was Enacted.

Even assuming the Court of Appeals was correct in suggesting that it would be unconstitutional for the Legislature to enact legislation conditioning a consequence on an agency determination, to the extent the determination were to occur after enactment of the legislation (which is denied), the statute would still be constitutional as applied in the context of prior FDA approvals. The Michigan courts have uniformly held that the Legislature may adopt by incorporation in a statute existing federal rules, statutes, or regulations. City of Pleasant Ridge v Governor, 382 Mich 225; 169 NW2d 352 (1969); Louis A Demute, Inc v Employment Security Commission, 339 Mich 713; 64 NW2d 545 (1954); People v Urban, 45 Mich App 255, 262; 206 NW2d 511 (1973); Radecki v

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Director of Bureau of Worker's Disability Comp, 208 Mich App 19; 526 NW2d 611 (1994).

Here, the drug at issue manufactured and/or sold by SmithKline was approved by the FDA in 1973. This approval has never been withdrawn. Thus, even if the Court of Appeals were correct in its analysis, MCL 600.2946(5) should be held valid to the extent it has consequences dependent on prior FDA approvals.

F. Alternatively, Even If Section 2946(5) Is A Delegation Of Legislative Authority, Which Is Denied, It Is A Proper Delegation Within The Confines Of The Constitution.

Section 2946(5), if in fact a statute delegating legislative power to make laws to another, is nonetheless within the confines of the Constitution. The Courts have repeatedly recognized in contexts other than tort liability that delegation is essential for the running of government. See Currin v Wallace, 306 US 1; 59 S Ct 379; 83 L Ed 441 (1939) (legislation must often be adapted to conditions involving details with which it is impracticable for the legislature to deal directly); People v Turmon, 417 Mich 638; 340 NW2d 620 (1983) (Legislature can delegate to the Board of Pharmacy the authority to classify controlled substances within legislatively established schedules with penal implications); Argo Oil Corp v Atwood, 274 Mich 47; 264 NW 285 (1936) (Legislature can delegate to the Secretary of State the authority to fix the amount of a bond required before it will issue a wholesale gasoline distributor's license); and Dept of Natural Resources v Seaman, 396 Mich 299; 240 NW2d 206 (1976) (Legislature can delegate to the Director of Conservation the authority to place restrictions on commercial fishing licenses).

In Argo Oil, the Supreme Court recognized that a delegation of authority is proper within limits:

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> It is too well settled to need the citation of supporting authorities that the legislature, within limits defined in the law, may confer authority on an administrative officer or board to make rules as to details, to find facts, and to exercise some discretion, in the administration of a statute. [274 Mich at 52.]

Even if section 2946(5) is a statute delegating to another the authority to administer a statute (which defendant denies as discussed above), the statute would still be a proper delegation of legislative authority. In People v Turmon, supra, the Supreme Court held that the Legislature could delegate its authority to add controlled substances to pre-existing schedules to the Board of Pharmacy despite the fact that penal consequences flow from violation of the board's rules. 417 Mich at 641. Noting that the "complexities of modern government necessitate that today many facets of traditionally 'legislative' power be exercised by administrative agencies", the Court found that the Legislature provided a proper framework to guide and direct the agency's action. Id. at 649, 645.

The Court in People v Turmon noted that this act grants the Board of Pharmacy the power to modify the original schedules established by the Legislature and provides for an eight-member board to consist of six registered pharmacists and two representatives of the general public. Id. at 645. The act outlines several factors that must be considered before any substance is added to, deleted from or reclassified among the schedules. The statute also establishes a scientific advisory commission to assist in the consideration of such factors. Id. at 646. The board may include a substance only after it finds the substance possesses certain characteristics. Id.

The Supreme Court in Turmon, found such provisions "clearly provide a proper framework to guide and direct agency action." In declaring the statute valid the Court recognized that the Legislature is the governmental body to declare policy:

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> However, the standard of review of legislative delegation does not differ when the statute involves criminal sanctions. The Legislature is not precluded from including penal sanctions in a statute which declares a legislative policy, articulates guidelines to effectuate the policy, and authorizes an executive agency to implement its purpose. [417 Mich at 650.]

As noted above, The Federal Food, Drug and Cosmetic Act, 21 USC 301-92, provides a comprehensive regulatory scheme over drug formulation, production, testing and labeling. See 21 CFR 300-369. Clearly, the FDA contains sufficient safeguards and guidelines to avoid an unconstitutional delegation of legislative power claim.

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CONCLUSION AND RELIEF REQUESTED

Defendant SmithKline Beecham Corporation submits that MCL 600.2946(5) is a legislative policy declaration of the standard of care owed by a drug manufacturer, for compliance with which tort liability will not lie, and which does not implicate or violate the constitutional prohibition on delegation of legislative authority.

Defendant SmithKline Beecham Corporation respectfully requests that this Honorable Court reverse the lower courts' denial defendants' motions for summary disposition. Defendant SmithKline Beecham Corporation further requests that this Court declare MCL 600.2946 to be constitutional and direct that summary disposition be granted to this defendant.

Respectfully submitted,

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STATE OF MICHIGAN

IN THE SUPREME COURT

ON APPEAL FROM THE COURT OF APPEALS
(Collins, P.J. (not participating) and Murphy and Jansen, J.J.)

TAMARA TAYLOR and LEE ANNE RINTZ, on behalf of themselves and all other similarly situated,

Plaintiffs-Appellees,

vs.

GATE PHARMACEUTICALS, A DIVISION OF TEVA PHARMACEUTICALS, USA, INC.,

Defendant,

SMITHKLINE BEECHAM CORP.,

Defendant-Appellant,

ZENITH GOLDLINE PHARMACEUTICALS, INC.; ABANA PHARMACEUTICALS, INC.; RICHWOOD PHARMACEUTICAL CO., INC.; ION LABORATORIES, INC.; MEDEVA PHARMACEUTICALS, INC.; A.H. ROBINS CO., INC.; WYETH-AYERST LABORATORIES CO.; AMERICAN HOME PRODUCTS CORP.; INTERNEURON PHARMACEUTICALS, INC.; CAMALL CO.; PEDRITO GALUPA, M.D.; and WILLIAM R. TUURI, M.D.,

Defendants. /

Supreme Court Docket No. 120624

AFFIDAVIT OF SERVICE

STATE OF MICHIGAN)
)SS
COUNTY OF WAYNE)

LYNN A. LASHER, being first duly sworn, deposes and says that she is employed with the firm of KITCH DRUTCHAS WAGNER DENARDIS & VALITUTTI, and that on the 27th day of AUGUST, 2002 she personally served:

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TWO COPIES of the following documents: **BRIEF ON APPEAL FOR SMITHKLINE BEECHAM CORPORATION, APPENDIX AND AFFIDAVIT OF SERVICE** by having same enclosed in an envelope with postage thereon fully prepaid and deposited in a United States postal receptacle.

Further, Affiant saith not.

LYNN A. LASHER

Subscribed and sworn to before me
this 27th day of AUGUST 2002

Notary Public, Wayne County, MI
My Commission Expires: 9/7/02

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